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510(k) Summary of Safety and Effectiveness
American Medical Systems, Inc.'s *Fascial-Anchoring System*
510(k) Number K010277

January 29, 2001

Submitter/Contact Person:
Avraham Biran / Elsa Linke
American Medical Systems, Inc.
10700 Bren Road West
Minnetonka, MN 55343
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Device Name and Classification:

Trade Name: Fascial Anchoring System
Classification Name: Implantable Clip and Applier
Common Name: fascial clip

Predicate Devices:
Boston Scientific Curvilinear Suture Placement Device (K973415); US Surgical Corp. Modified Endoscopic Fascia Stapler (K963999), Origin Medsystems Origin Tacker System (K944415) and Acufex Microsurgical's T-Fix and T-Bar (K942442 and K925573, respectively).

Device Description:
The Influence Fascial-Anchoring System has two components: a fascial clip, which is shaped as a rod and has a #1 polypropylene suture threaded through it and a small diameter, curved applier.

Indication for Use:
The *Fascial-Anchoring* System is intended for placement of a sutured clip in bladder neck suspension and transvaginal sling procedures for the correction of female stress urinary incontinence resulting from urethral hypermobility and/or intrinsic sphincter deficiency.

Technological Characteristics and Performance:
All materials used in the *Fascial-Anchoring System* are either commonly used in medical applications or have been proven to be biocompatible through biocompatibility testing. Bench testing has demonstrated that the device is safe and effective and that its performance is substantially equivalent to a 510(k)-cleared device.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAR 2 6 2001

Ms. Elsa A. Linke
Regulatory Affairs
American Medical Systems, Inc.
10700 Bren Road West
Minnetonka, Minnesota 55343

Re: K010277
Trade Name: Fascial-Anchoring System
Regulatory Class: II
Product Code: NEH
Dated: January 29, 2001
Received: January 30, 2001

Dear Ms. Linke:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the current Good Manufacturing Practice requirement, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic (QS) inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4595. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "http://www.fda.gov/cdrh/dsmamain.html".

Sincerely yours,

Miriam C. Provost

for Celia M. Witten, Ph.D., M.D.
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

INDICATIONS FOR USE

510(k) Number (if known): K010277

Device Name: *Fascial-Anchoring* System, consisting of the *Fascial-Anchoring* System Applier and Clips.

Indications for Use: The *Fascial-Anchoring* System is intended for placement of a sutured clip in bladder neck suspension and transvaginal sling procedures for the correction of female stress urinary incontinence resulting from urethral hypermobility and/or intrinsic sphincter deficiency.

(PLEASE DO NOT WRITE BELOW THIS LINE -CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)
(Division Sign-off)
Division of Reproductive, Abdominal, Ear, Nose and Throat, and Radiological Devices

510(k) Number K010277

Prescription Use ✓ OR Over the Counter Use_____
(Per 21 CFR 801.109)

Miriam C. Provost
(Division Sign-Off)
Division of General, Restorative
and Neurological Devices

510(k) Number K010277